### REMARKS

## Withdrawal of §102 and §103 Rejections Based on Ribier '166, Ribier '364, Sebag, Subbiah, and Ichinose

In the December 27, 2006 Office Action, the Examiner withdrew the previously raised §102 and §103 rejections against claims 1 and 3-20 based on U.S. Patent No. 5,650,166 (Ribier '166), U.S. Patent No. 5,925,364 (Ribier '364), U.S. Patent No. 5,411,742 (Sebag), U.S. Patent No. 6,150,381 (Subbiah), and U.S. Patent No. 5,702,691 (Ichinose), in light of the arguments presented by Applicants in the October 10, 2006 Appeal Brief. Specifically, the Examiner expressly acknowledged that:

- Ribier '166 fails to disclose a composition containing cholesterol sulfate and an exfoliant in the <u>amounts</u> claimed by claims 1 and 3-9;
- Ribier '364 and Sebag fail to provide adequate motivation to <u>combine an exfoliant</u> as taught by Sebag (i.e., salicylic acid) into the composition disclosed by Ribier '364 and therefore do not render claims 1, 3-4, 6-9, 11 and 18 obvious; and
- Ribier '166 fails to specifically teach or render obvious a composition having the cholesterol sulfate and amino sugar exfoliant in the <u>amounts</u> claimed by claims 13-20.

Applicants hereby thank the Examiner for her consideration of Applicants' arguments and her withdrawal of the previously raised §102 and §103 rejections.

### Response to the §112 Rejections

In the outstanding Office Action, the Examiner rejected then pending claims 1 and 3-20 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner asserted that the specification as originally filed does not provide adequate support for "<u>an integral mixture</u>" of cholesterol sulfate and exfoliant/amino sugar.

In response, Applicants have hereby amended independent claims 1, 13, 16, and 19, from which claims 3-12, 14-15, 17-18, and 20 depend by deleting the term "integral." The claim rejections under §112, first paragraph are therefore overcome.

## <u>Response to §103 Rejections Based on Abe '911, Shimada, Abe '314, Bernstein, Kitada, and Takahashi</u>

Claims 1, 3, 5, 13, and 16-19 were rejected under 35 U.S.C. §103(a) as allegedly obvious over the English Abstract of Japanese Patent Application No. 60-161911 to Abe et al. (hereinafter "Abe '911") in view of the English Abstract of Japanese Patent Application No. 59-013708 to Shimada et al. (hereinafter "Shimada").

Abe '911 discloses a cosmetic composition containing 0.01-5 wt% of cholesterol sulfate or salts thereof for improving dried skin, preventing aging of skin, providing skin with wetting characteristics, softness and luster by promoting water retention function of skin. However, nothing in Abe '911 teaches or suggests the use of an exfoliant or amino sugar, as positively recited by the claims of the present application. In the outstanding Office Action, the Examiner expressly conceded the deficiency of Abe '911 (see Office Action, page 7, lines 1-2), but attempted to remedy it by citing Shimada, which discloses a cosmetic composition containing 0.1-5 wt% of an amino sugar, such as N-acetyl-D-glycosamine, N-acetyl-D-galactosamine, D-glucosamine, D-galactosamine, and hydrochlorides and sulfates thereof, for moistening, emolliating, and activating the skin and giving smooth feeling, springiness and luster to the skin. Referring to In re Kerkhoven, 205 USPQ 1069 (CCPA 1980), which held that it is prima facie obvious to combine two compositions known to be useful for the same purpose to form a third composition to be used for the very same purpose, the Examiner asserted that because Abe '911 teaches use of cholesterol sulfate-containing composition for improving dry skin and wetting skin to promote softness and luster of skin, and because Shimada teaches use of N-acetylamino sugars for giving smoothness and moistness to skin and improving the feeling and luster of skin, it would have been obvious for one of ordinary skill in the art to provide the amino sugars disclosed by Shimada in the cholesterol sulfate-containing composition disclosed by Abe '911, with the expectation to provide an ingredient suitable for moisturizing and improving the luster of skin (see Office Action, page 7, lines 13-20 and page 8, lines 1-8).

Applicants respectfully disagree with the Examiner's assertions of obviousness, for the following reasons:

It has been well established that a prima facie case of obviousness can be rebutted by a "showing of facts supporting the opposite conclusion," which dissipates the prima facie holding and requires the examiner to "consider all of the evidence anew." In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984); and In re Rinehart, 531 F.2d 1048, 1052 (CCPA 1976). Rebuttal evidence

may show, for example, that the prior art *teaches away* from the claimed invention, <u>In re Geisler</u>, 116 F.3d 1465, 1471 (Fed. Cir. 1997); that the claimed invention achieved *unexpected results* relative to the prior art, *Id.*, at 1469-70; that objective evidence (e.g., commercial success) supports the conclusion that the invention would not have been obvious to a skilled artisan, <u>Piasecki</u>, 745 F.2d at 1475; or that the prior art did not enable one skilled in the art to produce the now-claimed invention, <u>In re Payne</u>, 606 F.2d 303, 314-15 (CCPA 1979).

Abe '911 expressly teaches that skin wetting agent and skin softener conventionally used in cosmetic compositions may <u>cause inhibition of normal physiological functions of skin</u>. One of the advantages of the cholesterol sulfate-containing cosmetic disclosed by Abe '911 lies in its capability of promoting water retention function of skin through normalizing functions between stratum corneum cells and through making structure of such cells dense, so that this cosmetic does not require a large amount of the conventional skin wetting agent and skin softener, and there is therefore no fear that it may inhibit normal physiological functions of skin (see the English Abstract of Abe '911). In contrast, Shimada teaches that amino sugars, such as N-acetyl-D-glucosamine and salts thereof, function to moisturize and soften the skin and thereby impart good gloss and tension to the skin (see the English Title and Abstract of Shimada provided by Derwent Patent Index). Therefore, the amino sugars disclosed by Shimada can be considered skin wetting agents or skin softeners, the use of which is expressly taught away by Abe '911, due to concerns described hereinabove. Therefore, a person ordinarily skilled in the art, after reading Abe '911 and Shimada, would not have been motivated to use the skin-moisturizing/softening amino sugars disclosed by Shimada in the cholesterol sulfate-containing composition disclosed by Abe '911, in light of the express teachingaway by Abe '911.

Further, the present invention, by combining cholesterol sulfate and an exfoliant, such as an amino sugar, achieves <u>an unexpected and surprising result</u>. As explained by the instant specification, cholesterol sulfate <u>retards desquamation</u> by enhancing the cohesion of the stratum corneum and thereby results in <u>increased stratum corneum layer thickness</u>, while the exfoliant, or more specifically, the amino sugar, acts in exactly the opposite manner by <u>desquamating the skin</u> and <u>thinning or reducing the thickness of the stratum corneum layer</u>. A person ordinarily skilled in the art would expect the impacts of these two components of opposite functions to cancel each other out when they are combined. However, surprisingly and unexpectedly, the combination of these two components of opposite functions achieves a

balanced result in nurturing the skin and improving/protecting the barrier of the stratum corneum. Such an unexpected and surprising result further rebuts the *prima facie* case of obviousness.

# Consequently, <u>the combination of Abe '911 and Shimada, as proposed by the Examiner</u>, <u>is not obvious and cannot be used to support rejections of claims of the present application</u>.

Claim 4, which depends from claim 3, was rejected under 35 U.S.C. §103(a) as allegedly obvious over Abe '911 in view of Shimada, and further in view of Japanese Patent Application Publication No. 05-051314 to Abe et al. (hereinafter "Abe '314").

As mentioned hereinabove, the combination of Abe '911 and Shimada as proposed by the Examiner is not obvious and cannot be used to support rejections of claims of the present application. Abe '314 was filed after Abe '911 by the same applicant (i.e., Kanebo Ltd.) who filed Abe '911. Specifically, Abe '314 discloses use of specific cholesterol sulfate salts, such as calcium, magnesium, sodium, and potassium salts, for promoting the water retention function of skin consistent with the teachings of Abe '911 (see the English translation of Abe '314, paragraph [0007]). Nothing in Abe '314 teaches or suggests use of the cholesterol sulfate salts in a manner different from that taught by Abe '911. More specifically, nothing in Abe '314 contradicts or modifies the teaching-away by Abe '911 from using skin wetting agents or skin softeners in the cholesterol sulfate-containing cosmetic composition. Therefore, Abe '314 cannot remedy the deficiency of Abe '911 and Shimada, and thus cannot support the rejection against claim 4 of the present application.

Claims 6-12, 14-15, and 20, which depend from claims 1, 13, and 19 respectively, were rejected under 35 U.S.C. §103(a) as allegedly obvious over Abe '911 in view of Shimada, and further in view of International Patent Application Publication No. 90/01323 to Bernstein (hereinafter "Bernstein"), Japanese Patent Application Publication No. 10-017458 to Kitada et al. (hereinafter "Kitada"), and/or Japanese Patent Application Publication No. 06-263627 to Takahashi et al. (hereinafter "Takahashi").

As mentioned hereinabove, the combination of the primary references Abe '911 and Shimada as proposed by the Examiner is not obvious and cannot be used to support rejections of claims of the present application. The secondary references, i.e., Bernstein, Kitada, and Takahashi, were cited by the Examiner for their respective disclosure of fatty acids, cholesterol, sclareolide, and protease inhibitors. <u>Therefore, the applied disclosure of Bernstein, Kitada, and Takahashi references cannot remedy the above-explained deficiency of Abe '911 and Shimada, and thus cannot support the rejections against claims 6-12, 14-15, and 20 of the present application.</u>

Based on the foregoing, Applicants hereby request the Examiner to reconsider, and upon reconsideration to withdraw, the §103 rejections of claims 1 and 3-20 of the present application.

#### Response to the Obviousness-Type Double Patenting Rejection

In the outstanding Office Action, the Examiner imposed a provisional obviousness-type double patenting rejection against claims 1 and 3-20 of the present application based on claims 1-21 of co-pending U.S. Patent Application No. 10/424,616 (hereinafter "the '616 Application"). Specifically, the Examiner asserted that claims 1 and 3-20 of the present application and claims 1-21 of the '616 Application are both drawn to "a skin/cosmetic composition containing cholesterol sulfate, fatty acids, and a sterol (such as cholesterol) and methods employing the compositions" and are therefore "not patentably distinct from each other" (see Office Action, page 26, lines 1-6).

Applicants respectfully disagree. Claims 1 and 3-20 of the present application are drawn to a <u>composition comprising a mixture of: (1) cholesterol sulfate or salts thereof and (2) an exfoliant or an amino sugar and methods of using the same. In contrast, claims 1-21 of the '616 Application are drawn to <u>a composition comprising: (1) cholesterol sulfate and (2) optionally</u>, a sunscreen, a self-tanning agent, or a combination of a fatty acid, a ceramide, and a sterol and methods of using the same. Therefore, the Examiner's assertion that claims 1 and 3-20 of the present application and claims 1-21 of the '616 Application are both drawn to a skin/cosmetic composition containing cholesterol sulfate, fatty acids, and a sterol (such as cholesterol) and methods employing the compositions is incorrect. Instead, claims 1 and 3-20 of the present application clearly and unequivocally recite an exfoliant or amino sugar, which are entirely absent from claims 1-21 of the '616 Application. In other words, claims 1-21 of the '616 Application fail to provide any basis, either express or implicit, for the exfoliant or amino sugar positively recited by claims 1 and 3-20 of the present application.</u>

Correspondingly, Applicants request the Examiner to reconsider, and upon reconsideration to withdraw, the provisional obviousness-type double patenting rejection against claims 1 and 3-20 of the present application.

Respectfully submitted,

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